LCQ14: Introduction of cutting-edge technological medical devices

Following is a question by the Hon Paul Tse and a written reply by the Secretary for Health, Professor Lo Chung-mau, in the Legislative Council today (March 26):

Question:

It has been reported that a businessman has earlier on donated two non-invasive, no-radiation histotripsy medical devices specifically designed for liver cancer treatment (the Device) to two teaching hospitals. However, it is suspected that the Device has been left idle and failed to benefit patients as the Hong Kong Special Administrative Region Government has all along failed to include it in the scope of services available to members of the public. The Device has ended up being transferred to private hospitals, and only private hospitals can use it to treat liver cancer patients. There are views pointing out that the incident has deprived grass-roots patients of the opportunity to use cutting-edge technologies for low-cost cancer treatment in an efficient manner. A Member of this Council has explicitly indicated that the situation has led to unfavourable perception among patients. In this connection, will the Government inform this Council:

(1) of the respective numbers of new cases of liver cancer diagnosed and deaths from liver cancer in Hong Kong in each of the past three years;

(2) whether private hospitals are required to register with or report to the Government in respect of the introduction of cutting-edge technological medical devices and techniques; of the Government's regulatory measures and system for the introduction or use of new technological medical devices by private hospitals, so as to ensure patient safety;

(3) as the private hospitals that have obtained the Device have already offered pricing packages for the use of the Device with coverage provided by insurance companies, and the Hospital Authority (HA) has pointed out that the Device is still at the clinical research/trial stage and is not yet qualified for use in clinical services, whether the Government has assessed if the aforesaid practice of the private hospitals is safe and whether it is contradictory to the public healthcare policy; and

(4) as a former Director of HA has pointed out in a newspaper that the length of time taken by HA to introduce a new technology depends on its complexity, and that six months' time is a bit short in the case of histotripsy, which is a cutting-edge technology, whether the Government will review if the time taken to introduce new technological medical devices is too long; whether it has policies to shorten the time for introducing new technological medical devices, so as to develop a high-end healthcare service economy (especially in the light of the huge demand from a large number of Mainlanders who intend

to come to Hong Kong for the use of new technologies in liver cancer treatment), and encourage more capable members of the community to invest in introducing and donate more cutting-edge technological medical devices, thereby benefiting patients (especially grass-□roots patients); if it has, of the details; if not, whether a study can be conducted expeditiously?

Reply:

President,

The Government of the Hong Kong Special Administrative Region is committed to complementing technological innovation with institutional innovation. Through a series of measures such as the setting up of the Hong Kong Centre for Medical Products Regulation for the purpose of implementing the "primary evaluation" and the establishment of the Greater Bay Area Clinical Trial Collaboration Platform, the Government has been enhancing Hong Kong's drug and medical device approval and clinical trial capabilities on all fronts, facilitating the translation of biomedical research results into clinical applications, expediting patients' access to advanced diagnostic and treatment services, and fostering new quality productive forces in biomedical technology, thereby promoting Hong Kong's development into an international health and medical innovation hub.

However, innovative medical products must be scientifically proven, including via clinical trials, with the support of reliable data to ascertain their safety and efficacy, and also compared with known standards before they may be approved for registration or made available for clinical application by healthcare professionals like medical practitioners. Clinical trials should be distinguished from clinical services – the former should not be arbitrarily marketed as clinical services before reaching their primary endpoints with analysed results. Currently, Hong Kong has implemented the Medical Device Administrative Control System, and the use of medical devices is subject to the clinical decisions of healthcare professionals like medical practitioners. The Health Bureau is expediting the study on legislating for the statutory regulation of medical devices for approval and registration purposes. Citizens who need to seek medical services due to illnesses should consult professionals including medical practitioners, and should not be influenced by other online advertisements or publicity through endorsements.

Multiple effective treatment methods for liver cancer are now available, including surgical local liver resection, minimally invasive local treatment (such as radiofrequency ablation, microwave ablation, stereotactic body radiation therapy (SBRT in short)), interventional therapy, anti-cancer drugs (such as chemotherapy, targeted therapy, immunotherapy), or a combination of the above therapies, while some liver cancer patients may also need and are suitable for liver transplantation. All these therapies are available in the public healthcare system. Medical teams of the Hospital Authority (HA) will provide appropriate treatment options according to individual patients' actual clinical conditions (such as cancer pathological classification and staging, tumour size and location, presence of extrahepatic metastasis, liver function grading, and the patient’s physical condition etc.).

As for the histotripsy medical device in question, it is a new technology in minimally invasive local treatment which is now undergoing clinical trials for local treatment of liver cancer. Its scope of application under research is limited to early primary small liver cancer (such as hepatocellular carcinoma, cholangiocarcinoma, neuroendocrine tumours) and locally treatable metastatic liver tumours. Not all liver cancer patients are suitable for this new therapy. Moreover, the US Food and Drug Administration's approval for this device as a new option for liver-directed therapy was based on animal model experiments as well as clinical trial data with postoperative complications and short-term (30-day) tumour ablation rate as primary endpoints to support the safety and efficacy of this therapy. The clinical trials have neither provided data on long-term local tumour recurrence/metastasis rates and patient survival rates, nor compared the therapy with existing standard minimally invasive local treatments. In this connection, this new therapy can be regarded as another new technological option for liver-directed minimally invasive local treatment at this very stage, yet its comparability or even superiority requires further clinical evidence. Attending medical practitioners have the responsibility to provide patients with recommendations on various appropriate treatment options including their benefits and risks in view of the best interests of the patients, especially when other existing standard treatment options that have been scientifically proven to be safe and effective are suitable for the patients' conditions. Inappropriate use of new technologies that have not yet been proven to be more effective may result in patients missing the opportunity for adopting existing standard treatment options.

The HA will be considering the safety and efficacy of the relevant device for the Asian population (especially for Hong Kong patients) subject to the evaluation of data to be obtained from clinical trials. The comparability and superiority of this new therapy in clinical use vis-à-vis existing standard treatment options still need to be ascertained through more clinical trials. Furthermore, the cost of consumables under this therapy is higher than that of existing standard minimally invasive local treatments (such as radiofrequency ablation). At this stage, there is no plan for the HA to introduce this therapy into its clinical service. The HA wishes to emphasise that this therapy is not the only option available to liver cancer patients, and thus there is no issue of public hospital patients "missing out treatment opportunities". As for private hospitals which have introduced this device for research or services, the attending medical practitioners will need to make clinical decisions based on their professional judgment on whether or not to use this new technology as the most appropriate treatment for patients.

In response to the various parts of the question raised by the Hon Paul Tse, our reply in consultation with the Department of Health (DH) and the HA is as follows –

(1) Based on the available data from the DH and the Hong Kong Cancer Registry of the HA, the number of new cases and registered deaths for liver cancer in the past three years are tabulated below –

Year	Number of New Cases	Number of Registered Deaths
2020	1 735	1 530
2021	1 771	1 447
2022	1 612	1 412

(2) and (3) Whether in public or private hospitals, clinical trials carry a certain degree of risk to the participants and should be conducted by registered healthcare professionals after informing the participants of the associated risks and obtaining their explicit informed consent. At present, even though there is no statutory provision prohibiting healthcare professionals from using new medical devices on patients, healthcare professionals have the professional responsibility to act in the best interests of patients when providing treatment, and ensure that all clinical trials are conducted with the explicit informed consent of patients.

At present, private hospitals must comply with a series of requirements including those under the Private Healthcare Facilities Ordinance (Cap. 633) (the Ordinance) and the Code of Practice for Private Hospitals (the Code of Practice) when conducting clinical research (including clinical trials).

Pursuant to the Ordinance, the licensee of a private hospital must appoint a chief medical executive to take charge of the day-to-day administration of the facility, as well as establish and keep in operation a Medical Advisory Committee (MAC); on the other hand, the Code of Practice stipulates that the MAC provides advice to the licensee on whether to permit the introduction of new clinical techniques. Apart from the latest medical evidence on the safety and efficacy of the clinical technique concerned, factors including the equipment required as well as training and clinical experience of healthcare and other supporting clinical staff must also be considered. Both the licensee and the chief medical executive of a private hospital have the responsibility to ensure that the advice of the MAC is properly implemented.

The Code of Practice also stipulates that equipment (including medical devices) used in private hospitals should be appropriately procured and properly installed, operated, maintained and calibrated in accordance with the manufacturer's recommendations. Staff using the medical devices should receive training on the safe and proper use of the relevant devices. For conducting clinical research, private hospitals are required to establish relevant policies, set up ethics committees for monitoring, and comply with the requirements of the Code of Professional Conduct for the Guidance of Registered Medical Practitioners issued by the Medical Council of Hong Kong regarding clinical research and other applicable laws.

Compliance with the Ordinance and the Code of Practice is a condition for issuance and renewal of licence for private hospitals. Private hospitals

that fail to comply with the relevant requirements may face regulatory actions.

(4) The HA has established robust mechanisms for evaluating and deciding on the introduction of new drugs, devices and other innovative treatments for public healthcare services. The safety of the treatment methods, whether there is sufficient evidence supporting their therapeutic effectiveness, the cost-effectiveness of such introduction, as well as comprehensive comparisons with existing treatment services have to be considered. When making consideration according to these mechanisms, the HA must ensure fairness and objectivity as well as prudent use of public resources. Also, the consideration process will not and should not be influenced by whether the treatment method is provided or sponsored by individual pharmaceutical or device manufacturers.

The HA will closely monitor medical technology developments, with experts regularly studying and reviewing treatment options for patients and the latest developments in clinical and scientific evidence of related technologies, while considering healthcare professionals' opinions and overseas developments to plan for the introduction of medical technologies. Meanwhile, the availability of relevant expertise, manpower and facilities, as well as complementarity with government policy directions, will also be taken into account. The application in the public healthcare system of new drugs and medical devices, and methods for treatment that are still in the clinical trial phase without sufficient clinical data should be handled in a very careful and prudent manner.